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The safety of acupuncture during pregnancy: a systematic review

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ABSTRACT

Objective

Although there is a growing interest in the use of acupuncture during pregnancy, the safety of acupuncture is yet to be rigorously investigated. The objective of this review is to identify adverse events (AEs) associated with acupuncture treatment during pregnancy.

Methods

We searched Medline, Embase, Cochrane Central Register of Controlled Trials, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Complementary Medicine Database (AMED) and five Korean databases up to February 2013. Reference lists of relevant articles were screened for additional reports. Studies were included regardless of their design if they reported original data and involved acupuncture needling and/or moxibustion treatment for any conditions in pregnant women. Studies of acupuncture for delivery, abortion, assisted reproduction or postpartum conditions were excluded. AE data were extracted and assessed in terms of severity and causality, and incidence was determined.

Results

Of 105 included studies, detailed AEs were reported only in 25 studies represented by 27 articles (25.7%). AEs evaluated as certain, probable or possible in the causality assessment were all mild/moderate in severity, with needling pain being the most frequent. Severe AEs or deaths were few and all considered unlikely to have been caused by acupuncture. Total AE incidence was 1.9%, and the incidence of AEs evaluated as certainly, probably or possibly causally related to acupuncture was 1.3%.

Conclusions

Acupuncture during pregnancy appears to be associated with few AEs when correctly applied.

ANALYSIS

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Background Information

Due to significant concerns about drug use, more pregnant women are turning to non-pharmacological treatments for a variety of problems that can arise during pregnancy. While a great deal of attention has been paid to the effectiveness of acupuncture for pregnancy related conditions and the safety of acupuncture in general, no other comprehensive reviews on the safety of acupuncture during pregnancy had been undertaken to the best of the authors' knowledge. In the general population, the risk of serious adverse reactions with acupuncture has been estimated as 0.01 per 10,000 acupuncture sessions and 0.09 per 10,000 individual patients (both generally regarded as 'very low').

Due to the limited treatment options available to pregnant women for pregnancy-specific or general health problems, solid evidence regarding the safety of acupuncture in this patient population is greatly needed. The goal of this study was to systematically review the literature pertaining to the safety of acupuncture for pregnant women; identifying and quantifying adverse events (AEs) associated with this treatment.

PERTINENT RESULTS

In the included articles (n = 105), detailed adverse event reporting was included in 27, no adverse events were mentioned in 55, and 22 studies reported no adverse events (AE). The most commonly treated conditions in the studies were low back pain and/or pelvic pain, followed by fetal malposition, nausea and vomiting, tension-type headaches, depression, dyspepsia, insomnia, emotional complaints, lateral epicondylitis, back pain, sciatica, rib flare, and symphysis pubis dysfunction. These conditions were most commonly treated with manual acupuncture, followed by moxibustion, manual and electro-acupuncture, auricular acupuncture with or without manual acupuncture, and manual acupuncture plus bee venom pharmacopuncture. The number of acupuncture sessions ranged from 2 to 40 over a period of 5 days to 8 weeks, with a variety of acupuncture points utilized, including meridian points, extra-meridian points, trigger/tender points and/or auricular points.

The 27 studies reporting on AEs reported 429 events out of approximately 22,283 sessions of acupuncture in pregnant women (1.9%). Of these, 322 AEs were regarded as mild, 6 as moderate, 99 as severe, 2 as death related to AE, and 2 were not classified due to lack of information. Causality was evaluated as certain in 144 AEs, probable in 15, possible in 132, unlikely in 124, and un-assessable in 14. All AEs evaluated as being certain, probable, or possible were also classified as mild or moderate severity. All severe AEs and deaths related to AEs were evaluated as unlikely to have been caused by acupuncture.

The mild AEs reported included (from most common to least common – bottom of the list gets down to n = 1 per event):

- Needle or unspecified pain
- Local bleeding
- Haematoma, tiredness, headaches, and/or drowsiness
- Worsened symptoms/condition
- Dizziness
- Discomfort at needling points
- Ecchymosis/bruising
- Uterine contraction with or without abdominal pain
- Unpleasant odour with or without nausea
- Throat Problems
- Heat or sweating
- Nausea
- Unpleasantness with treatment
- Feeling faint
- Sleep disturbance and excessive fatigue
- Irritability/agitation (n = 2 for next few AEs)
- Heaviness of arms
- Rash at needling points
- Feeling energized
- Local anesthesia
- Itching
- Unspecified problems
- Weakness (n = 1 from now till end of list)
- Altered taste
- Pressure in nose
- Transient ear tenderness
- Bed rest required
- Thirst
- Sadness
- Edema
- Tattooing of the skin at needling points
- Shooting sensation with intense paraesthesia down the leg to the foot
- Breech engagement
- Threatened preterm labour which spontaneously disappeared completely within a day followed by a normal labour in the 42nd week
- Fetus noted as small for date
- Multiple twists of the umbilical cord around the neck or shoulder

Moderate AEs reported included:

- Fainting (n = 5)
- Transient fall in blood pressure (n = 1)

Overall AE Risk Estimates:

The total incidence of AEs in the acupuncture group was calculated as 1.9%. This fell to 1.3% when

only those AEs considered to be certainly, probably, or possibly caused by acupuncture treatment were evaluated. Overall, the risk of mild or moderate events from acupuncture was estimated to be 1.5%. There were no serious AEs or deaths from acupuncture in 10,000 treatments. The authors also performed a sensitivity analysis, where they included poor outcomes from the studies that were not originally considered to be AEs to their calculation. From this, the incidence only rose to 4.8% (then back down to 1.9% for those AEs classified as certainly, probably, or possibly related to acupuncture treatment). These values are comparable to, or lower than, those found in the general population in previous studies (1-4).

CLINICAL APPLICATION & CONCLUSIONS

This review found that most AEs related to acupuncture during pregnancy were mild and transient and that serious AEs were very rare and unlikely to be caused by the acupuncture treatment. Overall, the incidence of AEs associated with acupuncture during pregnancy was found to be 131 per 10,000 treatments, or 1.3%. This is comparable, or lower than, the risk of AEs with acupuncture treatment in the general population, indicating that acupuncture is a safe modality to use during pregnancy. This information, along with information on effectiveness of acupuncture during pregnancy should be communicated to pregnant women to allow them to make a fully informed decision regarding their health care options during pregnancy.

STUDY METHODS

The authors searched the following databases from inception to February 2013 for relevant papers:

- Ovid Medline
- Cochrane Central Register of Controlled Trials
- Embase
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Allied and Complementary Medicine Database (AMED)
- Korean Studies Information Service System (KISS)
- Korea Institute of Science and Technology Information (KISTI)
- DBPIA
- Korea National Assembly Library
- Korean Traditional Knowledge Portal (KTKP)

The reference lists of the relevant articles were then screened for additional studies. All articles were assessed by two of the authors for inclusion and 105 articles were ultimately included in the review.

In order to be included, studies had to fulfill the following inclusion criteria:

- Original patient data was provided/included
- Subjects were pregnant women being treated for any condition
- Acupuncture treatment including needling or moxibustion was provided
- Adverse events were reported

Studies were excluded if they investigated the effect of acupuncture on delivery, abortion, assisted reproductive technologies, or postpartum conditions.

Classification of Adverse Events:

Adverse events (AEs) were classified into maternal and fetal outcomes and assessed for severity based on the Common Terminology Criteria for Adverse Events (CTCAEs) scale V.4.0. This scale grades adverse events into 5 categories:

- *Grade 1:* mild (asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated)
- *Grade 2:* moderate (minimal, local, or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily living)
- *Grade 3:* severe or medically significant but not immediately life-threatening (hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care or ADLs)
- *Grade 4:* life-threatening consequences (urgent intervention indicated)
- *Grade 5:* death related to adverse event

Two reviewers further evaluated the adverse events for causality, rating their relationship to the acupuncture treatment(s) as certain, probable/likely, unlikely, conditional/unclassified, and un-assessable/unclassifiable.

STUDY STRENGTHS / WEAKNESSES

Strengths

- Two separate authors extracted data from the articles and a third reviewer validated the data.
- When further information was needed about an article, the original authors were contacted if possible.

Weaknesses

- The quality of the data reporting was mostly deemed to be poor among the included studies.
- Appropriate information regarding obstetric complications was lacking in the articles, making it difficult to make any significant conclusions about these types of adverse events.

Additional References

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